

K964520

FEB 10 1997

**SUMMARY OF SAFETY AND EFFECTIVENESS
PARASCAN SCANNING DEVICE OR CBH-1 COLLIMATED BEAM
HANDPIECE FOR TREATMENT OF WRINKLES/RHYTIDES**

REGULATORY AUTHORITY:

Safe Medical Devices Act of 1990, 21 CFR 807.92

COMPANY NAME/CONTACT:

Lisa McGrath

Sr. Regulatory Affairs Specialist

Laserscope

3052 Orchard Parkway

San Jose, CA 95134-2011

(408) 943-0636

(408) 943-1454 FAX

DEVICE TRADE NAME:

- A. ParaScan™ Scanning Device
- B. CBH-1 Collimated Beam Handpiece

DEVICE COMMON NAME:

- A. Scanning Laser Delivery System
- B. Collimated Handpiece

Note: *Heraeus Surgical, Inc., including the LaserSonics product line, was acquired by Laserscope.*

000004

**SUMMARY OF SAFETY AND EFFECTIVENESS,
PAGE 2**

DEVICE CLASSIFICATION:

CO₂ laser systems have been classified as Class II (79 GEX) medical devices by the OB/GYN, General, Plastic Surgery and ENT Device Advisory Panels. To the best of our knowledge, scanning laser delivery systems and handpiece accessories have not been classified.

PERFORMANCE STANDARDS:

The ParaScan Scanning Device and CBH-1 Collimated Beam Handpiece comply with 21 CFR 1040.10 and 1040.11, FDA regulations for medical laser products, as applicable.

INDICATIONS FOR USE STATEMENT:

The ParaScan Scanning Device and CBH-1 Collimated Beam Handpiece are intended for soft tissue indications (CO₂ soft tissue clearances previously obtained by Heraeus Surgical). In addition, indications include treatment of wrinkles/rhytides; solar/actinic elastosis; keratoses; lentigos; laser skin resurfacing; laser resurfacing; laserabrasion; scar revision; warts; periorbital syringomas; epidermal nevi; rhinophyma; xanthelasma; actinic cheilitis and debulking benign tumors.

000005

**SUMMARY OF SAFETY AND EFFECTIVENESS,
PAGE 3**

COMPARISON WITH PREDICATE DEVICE:

The ParaScan Scanning Device was determined substantially equivalent by FDA on February 13, 1996 for all previously cleared LaserSonics CO₂ soft tissue surgical applications (510(k)955734). The CBH-1 Collimated Beam Handpiece is equivalent to the ParaScan Scanning Device beam collimator and handpiece.

000006